DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 20, 2015

Synthes USA Products, LLC
% Ms. Kate Larose
Manager, Regulatory Affairs
DePuy Synthes Spine, a Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K142838
Trade/Device Name: Synapse Occipital-Cervical-Thoracic (OCT) System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: December 22, 2014
Received: December 24, 2014

Dear Ms. Larose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142838

Device Name
Synapse Occipital-Cervical-Thoracic (OCT) System

Indications for Use *(Describe)*
The Synapse OCT System, including Synapse, OC Fusion and Axon, is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Synapse OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Axon and Synapse Systems may be connected to the Synthes Universal Spinal System using parallel connectors and tapered rods. The Synapse OCT System can also be linked to the titanium DePuy EXPEDIUM Spine System using the 3.5mm/5.5mm and 4.0mm/5.5mm titanium tapered rods.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – Synapse Occipital-Cervical-Thoracic (OCT) System

Name of 510(k) Sponsor:	Synthes USA Products LLC
Name of Presiding Company:	DePuy Synthes Spine, a Johnson & Johnson Company 325 Paramount Drive Raynham, MA 02767
510(k) Contact:	Kate Larose Manager, Regulatory Affairs Telephone: 508-828-2876 FAX: (508) 828-3797 Email: klarose@its.jnj.com
Date Prepared:	January 13, 2015
Trade Name:	Synapse Occipital-Cervical-Thoracic (OCT) System
Common Name:	Posterior, Cervical Pedicle Screw Spine Fixation Spinal Interlaminal Fixation Orthosis Posterior Cervical System
Classification:	Posterior, Cervical Pedicle Screw Spine Fixation Orthopaedic and Rehabilitation Devices Panel Unclassified; Pre-Amendment Device Product Code: NKG Appliance, Fixation, Spinal Interlaminal Orthopaedic and Rehabilitation Devices Panel Class 2 per 21 CFR 888.3050 Product Code: KWP
Predicate Device:	K062254- Medtronic Sofamor Danek's AXIS® Fixation System
Device Description:	The Synapse OCT System, including Synapse, OC Fusion and Axon consists of screws, hooks, rods, plates, transverse bars, parallel connectors, transconnectors, and locking screws. These implants are designed for fixation of the occiput, cervical, and/or upper thoracic spine (Occiput – T3). A complete OCT construct can be created by using components that have been previously cleared within the CerviFix, Axon, Synapse and OC Fusion Systems. The components of the Synapse OCT System are manufactured from Titanium Alloys, similar to the predicate device.
Intended Use / Indications for Use:	The Synapse OCT System, including Synapse, OC Fusion and Axon, is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis);

	tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Synapse OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the Axon and Synapse Systems may be connected to the Synthes Universal Spinal System using parallel connectors and tapered rods. The Synapse OCT System can also be linked to the titanium DePuy EXPEDIUM Spine System using the 3.5mm/5.5mm and 4.0mm/5.5mm titanium tapered rods.
Comparison of the technological characteristics of the device to the predicate device:	The Synapse OCT System achieves the same surgical objective as the predicate device. The subject devices and the predicate both utilize pedicle and/or lateral mass screws in the cervical spine coupled to a rigid longitudinal element to achieve immobilization and stabilization of cervical spinal segments as an adjunct to fusion. The key differences in technological characteristics are the cross sectional shape of the rigid longitudinal element, and the means of coupling the rigid longitudinal element to the implanted pedicle and/or lateral mass screws. These technological differences do not raise different questions of safety and effectiveness.
Performance Data	Published literature and bench testing per ASTM F1717 and ASTM F2706 (static compression bending, static torsion, dynamic compression bending, static tensile bending and dynamic torsion) demonstrate that the Synapse OCT System is substantially equivalent to the predicate device.